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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,115	07/03/2003	Lewis Sharps	S-9-6	4213

21394 7590 08/17/2005
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EXAMINER

COHEN, LEE S

ART UNIT PAPER NUMBER

3739

DATE MAILED: 08/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/613,115

Applicant(s)

SHARPS ET AL.

Examiner

Lee S. Cohen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2005.
 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32, 58 and 59 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-32, 58 and 59 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
 5) ☐ Notice of Informal Patent Application (PTO-152)
 6) ☐ Other: _____

DETAILED ACTION

Priority

The amendment to the priority information at page 1 of the specification still includes an inaccurate reference to Application No. 09/767,194 in lieu of 09/676,194. Further, the priority information in the specification, the application data sheet, and the parent application are inconsistent.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 12, the reference to one active heat delivery element is vague.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 14, 18, 20, and 21 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sluijter et al (5,433,739). The method includes placement of an electrode through a needle in the nucleus and applying Rf energy. Heating of the disc effects changes in the

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nucleus (column 13, lines 32-34). The electrode is translated in the disc to the desired location to effect the heating.

Claims 1, 3, 4, 10-12, 14, 18, 20, 21, and 58 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sharkey et al (6,007,570). The method includes placement of an electrode through a needle in the nucleus and applying Rf energy. Heating of the disc effects changes in the nucleus. The electrode is translated in the disc to the desired location to effect the heating. Applicant's attention is directed to col. 6, lines 38-40; col. 8, lines 63-65; col. 15, lines 30-40; col. 16, line 59; col. 17, lines 32-49; col. 21, lines 60-62; col. 22, lines 17-36; and col. 23, lines 5-30.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 28, 29, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sluijter et al (5,433,739). Movement of the probe to various locations within the disc would have been obvious to the skilled artisan to insure sufficient heating to effect the intended result. Further, particular dimensions are within the level of skill of the artisan to select to optimize performance of the method.

Claims 2, 9, 28, 29, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey et al (6,007,570). Movement of the probe to various locations within the disc would have been obvious to the skilled artisan to insure sufficient heating to effect the intended

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result. Further, the particular location of the return electrode on the probe and the particular dimensions are within the level of skill of the artisan to select to optimize performance of the method.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-32, 58, and 59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-56 of U.S. Patent No. 6,602,248.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are obvious changes in scope of the same inventive method.

Response to Arguments

Applicant's arguments filed August 4, 2005 have been fully considered but they are not persuasive. Applicant correctly points out that Sluijter et al and Sharkey et al perform other functions than disc decompression; however, the methods of these references also clearly decompress the disc. Disc decompression can be a result of shrinkage, ablation, coagulation, or other heating of the nucleus. Both references heat the nucleus which will result at least in shrinkage such that pressure on nerve roots are reduced. At column 13, lines 32-34, Sluijter et al

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discuss volumetric changes in the disc. Further, in Sharkey et al, at column 6, lines 36-40, disc material is removed to relieve pressure. Accordingly, the references are still deemed to anticipate the basic methodology.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lee S. Cohen whose telephone number is 571-272-4763. The examiner can normally be reached on Monday-Friday, 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lee S. Cohen
Primary Examiner
Art Unit 3739

LSC
August 10, 2005